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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,860	11/01/2005	Christopher P. Holmes	27519-0012US1	4443
7278	7590	07/15/2010	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			07/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,860	Applicant(s) HOLMES ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010 and 27 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/1/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed March 1, 2010 and April 27, 2010 are acknowledged. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 10, 11, 15, 25, 26, 30, 45 and 49 are cancelled. Claims 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 are pending.

As set forth below, the terminal disclaimers have not been accepted, and therefore the rejections are maintained.

Terminal Disclaimer

The terminal disclaimers filed on March 1, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Nos: 7,084,245 B2, 7,414,105 B2 and 7,528,104 B2 have been reviewed and are **NOT accepted**.

The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). It would be acceptable for a person, other than a recognized officer, to sign a terminal disclaimer, provided the record for the application includes a statement that the person is empowered to sign terminal disclaimers and/or act on behalf of the organization.

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Accordingly, a new terminal disclaimer which includes the above empowerment statement will be considered to be signed by an appropriate official of the assignee. A separately filed paper referencing the previously filed terminal disclaimer and containing a proper empowerment statement would also be acceptable.

Claim Objections

Claims 1 and 16 are objected to because of the following informalities: The claims recite the formula: $\text{---CO---(CH}_2\text{)}_m\text{---N---(CH}_2\text{)}_n\text{---CO---}$, however the valence of the central nitrogen is deficient. The examiner assumes it to be a typographical error, inadvertently omitting the hydrogen atom. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-49 and 57-72 of U.S. Patent No. 7,084,245 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and compositions of '245 anticipate, or render obvious, the instant claims. For example, the species of claim 72 is the elected species where the PEG is between 10k and 60k. In looking to the specification for the species that provide descriptive support for the claims, one finds the PEG to be 20k (columns 135 and 136), as in the elected species. It is noted that a certificate of correction has been granted cancelling claims 50-56, and thus are not included in the rejection above.

Claims 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 7,414,105 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and compositions of '105 anticipate, or render obvious, the instant claims. For example, the species of claim 3 is the elected species where the PEG is between 10k and 60k. In looking to the specification for the species that provide descriptive support for the claims, one finds the PEG to be 20k (columns 135 and 136), as in the elected species.

Claims 1-9, 12-14, 16-24, 27-29, 31-44, 46-48 and 50-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 15-34 of U.S. Patent No. 7,528,104 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and compositions of '104 anticipate, or render obvious, the instant claims. For example, the linker of claim 24 is a species/subgenus of instant claim 2

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and the linker of claim 19 is a genus embracing the species of instant claim 49, where one could envisage the instantly claimed species. In looking to the specification for the species that provide descriptive support for the claims, one finds a plurality of compounds that are within the confines of the instant claims, e.g. Table 3 and 4 compounds.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654